K080582

EXHIBIT 2

510(k) Summary K08

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February 25, 2008

Contact: Ashraf Stefan , CEO

MAY 15 2008

1. Identification of the Device:
   Proprietary-Trade Name: DDR MAK-800; the Model # DDR MAK-1000 FS, and the Model DDR MAK-1100 FA
   Classification Name: Stationary X-ray system,
   Product Codes Product Code 90 KPR and MQB
   Common/Usual Name: General purpose diagnostic X-ray Unit.

2. Equivalent legally marketed devices: This notification is for a MODIFIED device. This device COMBINES two 510(k) cleared devices, the SEDECAL X PLUS LP PLUS Universal Radiographic Systems K062335 AND a version of the DRtech Digital Panel, K080064. This combination is functionally identical to a SEDECAL cleared device, Sedecal URS LP X-Ray Units with Digital Detector, K042876..

3. Indications for Use (intended use) DDR Digital X-Ray Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

4. Description of the Devices: The DDR MAK-800 is the digital panel available alone for upgrading current systems. The DDR MAK-1000 FS is a complete system with a straight tube stand/detector combination. The DDR MAK-1100FA is a complete system with a "C-arm" shaped tube stand/detector combination which permits lateral positioning. These systems have been designed as a direct digital imaging system for use in hospital emergency rooms, imaging centers and all general radiology applications. The C-arm design maintains constant alignment between the x-ray tube and image receptor, regardless of C-arm tilt positions or image receptor angle. Its extraordinary flexibility makes the system ideal for all patients in standing, sitting or laying position, including those who are disabled or physically restricted. The DDR MAK-1100 digital flat panel detector provides advanced technology to capture radiographic images in a digital format almost instantly. The nearly 17 x 17 inch imaging area allows for the capture of chest and abdominal images without having to rotate the detector unit.

5. Safety and Effectiveness, comparison to predicate device. The results of bench, user, and standards testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

Characteristic	**Sedecal URS X-Ray Units with Digital Detector K042876**	**SEDECAL X PLUS LP PLUS Universal Radiographic Systems K062335**	**DDR MAK-800; the Model # DDR MAK-1000 FS, and the Model DDR MAK-1100 FA (This Submission):** **Combines two cleared devices: K062335 AND K080064**
Intended Use:	General purpose diagnostic X-ray unit	SAME	SAME
User Interface	Depends on Control Console option chosen. Mainly dedicated touch controls	Software Driven Touch Panel LCD, + IR remote control unit	Software Driven Touch Panel LCD, + remote control unit + remote console
Maximum output	Depends on model of generator chosen. Models available from 30 kW to 64 kW	SAME as original units.	SAME
Image Acquisition	Digital: CANON CXDI-50G. K031447	Film	Digital: DRTech Portable Digital Radiographic Detector K080064
Digital Panel Size	Up to 14" x 17" active area	N/A	17" x 17" or 14" x 17"
Digital Resolution	160 x 160 microns pixel pitch, with approximately 6 million pixels	N/A	139 x 139 OR 160 x 160 micron pixel pitch, either 6.8 or 7.8 million pixels.
Method of Control	Dedicated push button Controls	Software Driven Touch Panel LCD, +IR remote control unit	Software Driven Touch Panel LCD, +IR remote control unit and control room interface box.
Collimator	Manual R302/A	Manual R302/A and Automatic available	SAME

7. Conclusion

After analyzing bench, user, and standards testing data, it is the conclusion of Medicatech USA that the DDR MAK-800; the Model # DDR MAK-1000 FS, and the Model DDR MAK-1100 FA Radiographic Systems with Digital Detectors are as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

Medicatech USA
% Mr. Daniel Kamm, P.E.
Principal Consultant
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K080582
Trade/Device Name: Models # DDR MAK-800, DDR MAK-1000 FS, and DDR MAK-1100 FA
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: February 27, 2008
Received: March 27, 2008

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080582

Device Name: Model # DDR MAK-800; the Model # DDR MAK-1000 FS, and the Model DDR MAK-1100 FA.

Indications For Use:

Indications for Use: The DDR Digital X-Ray Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080582